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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/987,482

11/14/2001

Pooman Bhandari

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7065

22428

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04/09/2004

FOLEY AND LARDNER
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3000 K STREET NW
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EXAMINER

PARAS JR, PETER

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 04/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/987,482	Applicant(s) BHANDARI ET AL.	
	Examiner Peter Paras, Jr.	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) 2,3,5-9,11,13-18 and 20-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4,10,12,19 and 37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Applicant's amendment received on 2/3/04 has been entered. Claims 1, 4, 10, 12 and 19 have been amended. New claim 37 has been added. Claims 1-37 are pending. Claims 1, 4, 10, 12, 19 and 37 are under current consideration.

Election/Restrictions

Claims 2-3, 5-9, 11, 13-18, and 20-36 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the response filed on 4/28/03.

This application contains claims drawn to an invention nonelected with traverse in the response filed on 4/28/03. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Drawings

The drawings filed on 2/3/04 are accepted.

Specification

The previous objections to the specification are withdrawn.

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Claim Objections

The previous objections to claims 10 and 19 are withdrawn in light of the amendments to the claims.

Priority

It is noted the instant application claims priority to provisional application 60/276,483, filed on March 19, 2001. While the priority claim has been perfected since it was made in both the declaration and application data sheet, the first line of the specification does not contain a priority claim to the provisional application. Although not required, it is suggested for completeness that the first line of the specification be amended to set forth the priority claim to the provisional application.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The previous rejection of claims 1 and 19 under 35 U.S.C. 101 is withdrawn in view of the claim amendments.

Claim Rejections - 35 USC § 112, 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The previous rejection of claims 1, 4, 10, 12 and 19 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in light of the amendments to the claims.

Claims 1, 4, 10, 12, 19, and 37 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a transgenic *Drosophila* whose genome comprises a nucleotide sequence encoding the amino acid sequence set forth in SEQ ID NO: 1, wherein said transgenic *Drosophila* exhibits abnormal development of dorsal tergites that lack pigmentation, does not reasonably provide enablement for all other transgenic *Drosophila* embraced by the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The previous rejection is maintained for the reasons of record advanced on pages 8-12 of the Office action mailed on 11/3/03.

Applicant's arguments filed 2/3/04 have been fully considered but they are not persuasive. Applicants have argued the exemplified transgenic *Drosophila* exhibits considerably more than abnormal development of dorsal tergites that lack pigmentation. Applicants assert the specification and drawings clearly establish a wider range of phenotype changes, including changes of the eyes, wings and legs.

In response, the Examiner maintains the specification has not provided guidance correlating expression of the nucleotide sequence encoding the amino acid sequence set forth in SEQ ID NO: 1 with the full breadth of developmental abnormalities as recited

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in the claims. It is further maintained the working examples provided by the instant specification have only enabled the breadth of the recited phenotypes to the extent of abnormal development of dorsal tergites that lack pigmentation. See pages 9-11 of the Office action mailed on 11/3/03 also see Bhandari on pages 10-11. It is further maintained that phenotypes resulting from expression of a transgene are unpredictable. This is because the level and specificity of transgene expression as well as the resulting phenotype are directly dependent on the specific transgene construct. For example, the individual gene of interest, promoter (it is interesting to note that the claims as written do not recite a particular promoter that directs expression of the APC transgene; it is suggested that the claims be amended to include a promoter in operable linkage with the transgene), enhancer, coding, or non-coding sequences present in the transgene construct, the specificity of transgene integration into the genome, are all important factors in controlling the expression of a transgene in the production of transgenic animal which exhibits a resulting phenotype. See page 10. Although claim 37 recites three promoters that could potentially direct expression of the nucleotide sequence encoding the amino acid sequence of SEQ ID NO: 1, the claim merely requires the presence of the three promoters in the *Drosophila* genome. There is no requirement for the promoters to be in operable linkage to the nucleotide sequence encoding the amino acid sequence of SEQ ID NO: 1. Finally, the claims now require that the developmental abnormalities induced by expression of the protein having the amino acid sequence set forth in SEQ ID NO: 1 are similar to those exhibited by flies [*Drosophila* presumably and not house flies] carrying mutations in the *Drosophila* wingless gene. The specification

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however, has not provided guidance or relevant teachings with regard to which of the developmental abnormalities resulting from wingless mutations are exhibited by the instantly claimed transgenic *Drosophila*. It is suggested the specific developmental abnormalities exhibited by the claimed transgenic *Drosophila* be recited in the claims. Merely reciting that the claimed transgenic *Drosophila* exhibit similar developmental to mutant wingless flies is not sufficient.

Accordingly, the rejection is maintained for the reasons of record.

Claim Rejections - 35 USC § 112, 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 4, 10, 12, 19, and 37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The previous rejection of claim 4 as being incomplete as written is maintained for the reasons of record advanced on page 13 of the Office action mailed on 11/3/03.

While the claim has been amended, its steps still do not relate back to the preamble in a positive process. For example the preamble of the claim is directed to a method for selecting a compound for pharmacological activity, which potentially inhibits or enhances the developmental abnormalities induced by expression of the protein having SEQ ID NO: 1 while the steps of the method result in screening for changes of the phenotype.

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Accordingly, the rejection is maintained for the reasons of record.

The following new grounds of rejection under 35 U.S.C. 112, 2nd paragraph have been necessitated by the claim amendments:

Claim 1 is indefinite as written. The claim requires that developmental abnormalities, exhibited by the claimed transgenic *Drosophila* and induced by expression of the protein are similar to those exhibited by flies carrying mutations in *Drosophila* wingless gene. The claim is indefinite because the specification has not defined the similarities between developmental abnormalities. Therefore the similarity between the developmental abnormalities is not understood. It is also not understood if similarities are shared between all or only certain developmental abnormalities. Claims 4, 10, 12, 19, and 37 depend from claim 1.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Peter Paras, Jr., whose telephone number is (571) 272-0732. The examiner can normally be reached Monday-Friday from 8:30 to 4:30 (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at 571-272-0804. Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Official Fax Center number is (703) 872-9306.

Inquiries of a general nature or relating to the status of the application should be directed to Dianiece Jacobs whose telephone number is (571) 272-0532.

Peter Paras, Jr.

PETER PARAS, JR.
PRIMARY EXAMINER

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